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[FR Doc. 99–9427 Filed 4–14–99; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N–0337, 96N–0420, 95N–0259, and 90P–0201]

RIN 0910–AA79

Over-The-Counter Human Drugs; Labeling Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of March 17, 1999 (64 FR 13254). The final rule established a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products. The document was inadvertently published with an incorrect effective date. This document corrects that error.

DATES: Effective April 15, 1999, the effective date of the final rule published on March 17, 1999 (64 FR 13254) is corrected to May 16, 1999.

FOR FURTHER INFORMATION CONTACT: Debra L. Bowen, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–560), 5600 Fishers Lane, Rockville, MD 20852, 301–827–2222, or email ''BOWEND@cder.fda.gov''.

SUPPLEMENTARY INFORMATION: In FR Doc. 99–6296, appearing on page 13254 in the **Federal Register** of Wednesday, March 17, 1999, the following correction is made:

1. On page 13254, in the first column, under the ''**Dates**'' section ''*Effective Date*: April 16, 1999.'' is corrected to read ''*Effective Date*: May 16, 1999.''

Dated: April 12, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–9520 Filed 4–14–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Dichlorvos Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The supplemental NADA provides for veterinary prescription use of additional dichlorvos tablet sizes for the treatment of certain worm infections in cats and puppies and for the treatment of dogs and kittens.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, is the sponsor of NADA 48–271 that provides for veterinary prescription use of Task® (dichlorvos) tablets for cats and puppies for removal and control of certain intestinal roundworms and hookworms. The firm filed a supplemental NADA that provides for the use of 10- and 20-milligram (mg) dichlorvos tablets, in addition to 2- and 5-mg tablets, in cats and puppies, and for the use of dichlorvos tablets in dogs and kittens. The supplemental NADA is approved as of March 4, 1999, and the regulations are amended by revising 21 CFR 520.600(i) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the list of sponsors of approved applications in 21 CFR 510.600(c) is amended to reflect the sponsor's current zip code.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''Boehringer Ingelheim Vetmedica, Inc.'' and in the table in paragraph (c)(2) in the entry for ''000010'' by removing ''64502'' and adding in its place ''64506–2002''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Section 520.600 is amended by revising paragraph (i) to read as follows:

§ 520.600 Dichlorvos.

* * * * *

(i) *Conditions of use in dogs, cats, puppies, and kittens.* (1) Each tablet contains 2, 5, 10, or 20 milligrams of dichlorvos.

(2) It is administered orally at 5 milligrams of dichlorvos per pound of body weight.

(3) Dogs and puppies: Removal and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(4) Cats and kittens: Removal and control of intestinal roundworms